

Dated 31 August 2021

(1) TANDEM NANO LTD

(2) MEDICINES PATENT POOL

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PATENT AND KNOW-HOW LICENCE

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THIS AGREEMENT ("Agreement") dated 31 August 2021, is made BETWEEN:

- (1) **Tandem Nano Ltd.** a company incorporated under the laws of England and Wales with company number 08949503 and whose registered offices are at Suite 11b, Liverpool Science Park, Mount Pleasant, Liverpool L3 5TF, United Kingdom ("TNL");
- and
- (2) **Medicines Patent Pool Foundation** a not for profit charitable foundation registered under the laws of Switzerland, and having its principle place of business at Rue du Varembe 7, 1202 Geneva Switzerland ("MPP").

Each of TNL and MPP is referred to in this Agreement as a Party. TNL and MPP are collectively referred to in this Agreement as the Parties.

## Background

- I. MPP is a non-profit organisation with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property on those medicines.
- II. TNL is the exclusive holder of rights to long-acting injectable technologies ("LAI") which may provide efficacious exposure to drugs relevant to tuberculosis ("TB"), malaria, or hepatitis C virus ("HCV") for an extended period of time, and therefore may help reduce the associated costs of treatment. Under agreement with Unitaid (the "Unitaid Agreement"), TNL is obligated to license this technology to MPP in order to maximise impact and to reach as many people living with malaria, TB, or HCV as possible. Both Parties acknowledge that the key objective of this Agreement is to ensure that Licensed Products are made widely available as quickly as possible and on a continuing basis, at an affordable and sustainable price, to the Public Sector of Low- and Middle-Income countries ("LMICs") and in sufficient quantities to meet the needs of those countries (the "Access Objective"). TNL acknowledges that in High Income Countries ("HICs"), access to drugs in low income groups can also be a challenge and TNL's licensing strategy for HICs aims to be socially responsible.
- III. The rights afforded under this Agreement will allow MPP to enter into sub-licensing agreements with third parties, such as funders, product development partnerships, and pharmaceutical manufacturers and distributors to develop and manufacture long-acting formulations of specified pharmaceutical products for public health purposes under the rights described in this Agreement.
- IV. The intent of this Agreement is to provide access to Licensed Technology, and not to create any non-intellectual property-related barriers.

## Agreement

### 1. Interpretation

- 1.1 In this Agreement the following expressions have the meaning set opposite:

**Affordable Price:** means the maximum price at which a Final Product may be offered for sale in the Territory, reflective of the lowest, sustainable, competitive price level for a Final Product, to be agreed upon between Unitaid and TNL in accordance with the

terms of the Unitaid Agreement and notified by TNL to MPP as soon as reasonably possible.

**Affiliate:** means, in relation to a Party, any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such Party. For the purposes of this definition, "control" shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of a Party hereto are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.

**Change in Control:** means:

- i. the acquisition after the Effective Date, directly or indirectly, by any person or entity, of the beneficial ownership of more than fifty percent (50%) of the voting share capital of the relevant entity or the ability to direct the casting of more than fifty percent (50%) of the votes exercisable by the relevant Party;
- ii. a merger, consolidation or other similar transaction involving the relevant Party; or
- iii. the sale, transfer or other disposition (in one transaction or a series of transactions) of all or substantially all of the assets of the relevant Party.

**Commercialisation Agreement:** means an agreement executed by MPP and a Commercialisation Partner pursuant to this Agreement and under the terms and conditions set forth in Schedule 4 to this Agreement.

**Commercialisation Partner:** means any firm, corporation, partnership, limited liability company, business trust, joint venture, or other form of business organization to be selected by the MPP to enter into a Commercialisation Agreement under the terms and conditions outlined in Schedule 4 to this Agreement.

**Confidential Information:** means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by any Party or any of its Affiliates, or has otherwise become known to a Party or any of its Affiliates, as well as any other information and materials that are deemed confidential or proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information of TNL will include the Licensed Know-How.

**Development Agreement:** means an agreement executed by MPP and a Development Partner pursuant to this Agreement and under the terms and

- conditions set forth in Schedule 3 to this Agreement.
- Development Partner:** means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity or other form of business organization to be selected by the MPP to enter into a Development Agreement under the terms and conditions set forth in Schedule 3 to this Agreement.
- Effective Date:** means the date of the last signature to this Agreement.
- Encumbrance:** means any legal obligations to any third party (including but not limited to research funders or collaborators) or rights, interest or objections of an inventor, their department or faculty, that would in TNL’s sole opinion restrict or adversely affect its ability to grant rights over the intellectual property; and any reference to “unencumbered” shall be construed accordingly.
- Field:** means the prevention and/or treatment of malaria, TB or HCV.
- Final Products:** means long-acting formulations of the following existing medicinal products developed using University of Liverpool’s proprietary emulsion-templated freeze drying technology: (i), atovaquone (or other relevant combination) for malaria chemoprophylaxis (subject to Unitaid’s formal written approval in accordance with the terms of the Unitaid Agreement) ;(ii) rifapentine and a novel isoniazid prodrug for prevention of TB; (iii) glecaprevir and pibrentasvir for treatment of HCV; and (iv), bedaquiline and/or delamanid for the prevention of TB (subject to Unitaid’s formal written approval in accordance with the terms of the Unitaid Agreement). For the avoidance of doubt, “Final Products” means all of the products and “Final Product” means any one of them, as the context requires.
- High Income Countries:** means all high-income countries in accordance with the World Bank country classification at the Effective Date.
- Improvement:** means any new or improved process, any new or improved manufacturing techniques or any further invention or know-how which relate to the manufacture or formulation of the Licensed Products, or incorporate or are based on the Licensed Technology, developed by or on behalf of an MPP Licensee.
- Licensed Know-how:** means all technical information or know-how known to or controlled by TNL as of the Effective Date (including, without limitation, all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control and testing procedures) that is reasonably necessary for the making of Licensed Products, as well as any other modification or improvement of such technical information or know-how known to or controlled by TNL and unencumbered after the Effective Date.

<b>Licensed Patents:</b>	means any and all patents and patent applications describing the emulsion-templated freeze drying technology, the long-acting formulations as used in the Final Products, or any other intellectual property reasonably necessary for the making of the Final Products and that: (i) was filed by the University of Liverpool and transferred or assigned to TNL on or before the Effective Date; or (ii) is filed by the University of Liverpool and transferred or assigned to TNL after the Effective Date. The Licensed Patents include the patents and patent applications set out in Schedule 1, as may be amended from time to time, including any continuations, continuations in part, extensions, reissues, divisions, and any supplementary protection certificates and similar rights deriving priority from any of these.
<b>Licensed Product:</b>	means any Final Product which entirely or partially uses the Licensed Technology in either its development, manufacture, regulatory approval or whose manufacture, use or sale would constitute an infringement of any patent claim within the Licensed Technology.
<b>Licence Report:</b>	means the report set forth in Clause 6 to be provided annually by MPP to TNL.
<b>Licensed Technology:</b>	means the Licensed Patents and the Licensed Know-how.
<b>Low- and Middle-Income Countries:</b>	means all low- and middle-income countries according to the World Bank country classification as at the Effective Date; and reference to "LMICs" shall be construed accordingly.
<b>Minimum Supply Targets:</b>	means any targets agreed between Unitaid and TNL in accordance with the terms of the Unitaid Agreement in relation to minimum production capacity, minimum production capacity, minimum annual production volumes, maximum order lead time for delivery and/or minimum order quantity for a Final Product, each for the benefit of the Public Sector in the Territory.
<b>MPP Licensee:</b>	means Commercialisation Partner and Development Partner.
<b>Public Sector:</b>	means (a) the following organizations to the extent that they are not for profit organizations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v)

Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and (vi) agencies based outside of an applicable country to the extent that they are supplying Licensed Products in the Territory, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) above;

- Private Sector:** means any entity that is not included in the Public Sector;
- Stage Gates:** means the product development stage gates (individually, “SG”) established in the Unitaid Agreement to review progress towards completion of the Final Products.
- Stage Gate Framework:** means the framework as established in the Unitaid Agreement to set out the Stage Gates used to monitor progress towards development of the Final Products.
- Sub-Licence Agreement:** means the Development Agreement and/or the Commercialisation Agreement;
- Territory:** means the countries set out in Schedule 2., provided however that additional countries may be added pursuant to the Parties coming to agreement on commercialisation strategy as described in Section 2.7.

## **2. GRANT OF LICENCE AND RESERVATION OF RIGHTS**

- 2.1. Subject to the terms of this Agreement and with effect from the Effective Date, TNL grants to MPP:
- 2.1.1. a non-exclusive, non-transferable worldwide licence under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 3, to Development Partner(s) to develop, or have developed, Licensed Technology into Licensed Products in the Field; and
- 2.1.2. a non-exclusive, non-transferable, royalty-free worldwide licence under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 4, to Commercialisation Partner(s) to make, have made, use, offer for sale, sell, have sold, export or import the Licensed Products in the Field and exclusively for administration to patients in the Territory.
- 2.2. For the avoidance of doubt no rights are afforded to MPP under this Agreement for MPP or MPP Licensees to:
- 2.2.1. use the Licensed Technology outside the Field; or

- 2.2.2. offer for sale, sell, have sold or otherwise commercialise Licensed Products for use outside the Territory; or
  - 2.2.3. offer for sale, sell, have sold or otherwise commercialise the Licensed Products to, or for use by, the Private Sector; or
  - 2.2.4. have any right, title or interest to any intellectual property unless otherwise explicitly stated; or
  - 2.2.5. in the case of MPP, to directly practice such licences or otherwise exploit the Licensed Technology for any other purpose other than to grant sub-licences under Clause 3.1.1 and 3.1.2 of this Agreement.
- 2.3. Notwithstanding anything contained in this Agreement, it shall not be a breach of this Agreement for MPP, or MPP Licensees, to:
  - 2.3.1. supply to a country where a compulsory licence has been issued by the government of such country or;
  - 2.3.2. conduct any activities where such activities would not infringe a Licensed Patent granted and in force, or do not rely on or use the Licensed Know-How.
- 2.4. TNL reserves all rights not expressly granted to MPP under this Agreement, including (without limitation) the right to enter into separate licensing agreements with Commercialisation Partners for HICs with measures to protect volumes destined for purchase by the Public Sector in LMICs.
- 2.5. During the Term of this Agreement, the Parties will consider in good faith whether it may be possible to expand the Agreement or grant a separate licence to MPP allowing for the grant of sub-licences of the Licensed Technology to industry partners seeking to use it for the purposes of developing and/or commercializing additional products for the treatment of diseases in LMICs.
- 2.6. Upon reaching the last pre-clinical proof of concept stage gate unlocking for a particular Final Product as described within the Stage Gate Framework, the Parties will confer and come to mutual agreement on the question of whether a Development Partner is necessary for the development of that Licensed Product, or alternatively whether the Development Partner can be bypassed in favor of proceeding directly from contract manufacturer to Commercialisation Partner(s). For clarity, the last pre-clinical proof of concept stage gates for each Final Product are as follows: (a) atovaquone LAI: SG1; (b) rifapentine/isoniazid prodrug LAI: SG4; (c) glecaprevir/pibrentasvir LAI: SG6. In the event that a bedaquiline and/or delamanid LAI is workstream triggered under the Unitaid Agreement, the Parties will confer to determine the appropriate timing for review under this section.
- 2.7. Upon reaching clinical proof of concept stage gate unlocking for a particular Final Product as described within the Stage Gate Framework, the Parties will confer and come to mutual agreement as to the optimal commercialisation strategy for that Licensed Product, including, where a Development Partner is agreed to be necessary, incentive mechanisms to bring the Licensed Product to market promptly and at a low sustainable price. Possible commercialisation models to be explored include, for example, the establishment of a public sector/private market segmentation with royalties, and/or exclusive or semi-exclusive access to HICs on a royalty-bearing basis, provided that the amount of royalties remain reasonable in line with industry practices. Upon coming to mutual agreement, the Parties will amend the

Agreement accordingly. For clarity, the clinical proof of concept stage gates for each Final Product are as follows: (a) atovaquone LAI: SG2; (b) rifapentine/isoniazid: SG5; (c) glecaprevir/pibrentasvir LAI: SG7. In the event that a bedaquiline and/or delamanid LAI is workstream triggered under the Unitaid Agreement, the Parties will confer to determine the appropriate timing for review under this section.

### **3. RIGHT TO SUB-LICENSE TO MPP LICENSEES**

3.1. MPP may grant sub-licences and may disclose to MPP Licensees only such of the Confidential Information as is necessary for the exercise of the rights sub-licensed, subject in each case to the following conditions:

3.1.1. MPP and TNL will mutually agree on suitable MPP Licensees within 30 days of MPP proposing a potential MPP Licensee, where a potential MPP Licensee is deemed to be mutually agreed unless otherwise noted in writing by TNL stating the grounds and the mitigation approach; and

3.1.2. MPP will ensure that Commercialisation Partners selected possess or will possess prior to any applicable activities relating to the Licensed Products sufficient known sources of supply and production capacity to ensure continuity of supply of the Licensed Product to the Public Sector in accordance with Minimum Supply Targets, provided that TNL shares the Minimum Supply Targets with MPP in a timely manner, and

3.1.3. MPP will not enter into Development Agreements or Commercialisation Agreements for Licensed Products prior to agreement between University of Liverpool and Unitaid on the Specific Access Commitments for such Licensed Products; and

3.1.4. MPP provides TNL with a copy of each Sub-Licence Agreement together with a summary of the same, within 10 days after its grant; and

3.1.5. the MPP Licensee accepts obligations and conditions consistent with those in this Agreement including Schedule 3 and Schedule 4 (as applicable); and

3.1.6. MPP will ensure that the Sub-Licence Agreement(s) will grant to TNL a non-exclusive, perpetual, worldwide, royalty-free license to use any Improvement; and

3.1.7. MPP will ensure that Sub-licence Agreements contain indemnifying obligations against any loss, damages, costs, claims or expenses which are awarded against or suffered by TNL, its officers, employees, sub-contractors and agents as a result of any act or omission of the MPP Licensee; and

3.1.8. TNL will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Sub-licence Agreement(s).

3.2 MPP agrees to monitor compliance of each MPP Licensee. Such monitoring shall include:

3.2.1 reviewing with all reasonable skill and care any reports provided to MPP by the MPP Licensee under the relevant sections of the Sub-Licence Agreement;

3.2.2 fully exercising the audit right set out in the Sub-Licence Agreement(s) as soon as MPP has reasonable cause to believe (or as soon as TNL and MPP have agreed that they have reasonable cause to believe) an audit is necessary.



- 3.3 If MPP becomes aware of any act or omission of an MPP Licensee which constitutes a breach of the relevant Sub-Licence Agreement, the MPP shall notify TNL immediately and (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sub-Licence Agreement, direct the relevant MPP Licensee in writing to cure the breach, with a simultaneous copy of that writing to TNL; and (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sub-Licence Agreement, and in each case if so requested by TNL, procure the termination of the relevant Sub-Licence Agreement in accordance with its terms.
- 3.4 TNL shall provide the Minimum Supply Targets agreed with Unitaid to MPP at the earliest opportunity.

#### **4. LICENSED KNOW-HOW**

- 4.1. For each Development Agreement and/or Commercial Agreement executed with an MPP Licensee, TNL will make an initial transfer to MPP for use by an MPP Licensee, of the Licensed Know-how that TNL is free to disclose within 30 days of a request from MPP. Further transfer to MPP of Licensed Know-how may occur during the sub-license in accordance with Clause 7 of this Agreement.

#### **5. PUBLICITY AND PUBLICATION**

- 5.1. The Parties agree that neither Party will issue a press release or public announcement concerning the transactions contemplated hereby without the advance written consent of the other Party (such consent not to be unreasonably withheld or delayed). If either Party intends to issue a press release, it shall submit a draft of such proposed press release to the other Party at least five (5) business days prior to the date such Party intends to issue the release. After any initial press release or public announcement is made, however, each Party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

#### **6. REPORTING**

MPP will send to TNL within 30 business days following the end of each calendar year, a written report setting forth each Licensee's (a) Licensed Products development pipeline, (b) status of development of each Licensed Product in development, (c) regulatory filing plan for each Licensed Product, and (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been obtained for any Licensed Product.

#### **7. TNL TREATMENT ADVANCES FOR MALARIA, TB, OR HCV**

- 7.1. TNL will communicate in writing to MPP within a reasonable time, but in any case not to exceed 120 days, any technical development that may improve the treatment of TB, malaria, or HCV, which TNL comes to hold exclusive rights to and is free from any Encumbrances. TNL's obligation to communicate technical developments according to Clause 7.1 shall expire on the fifth anniversary of the Effective Date unless renewed or extended in writing.

- 7.2. Upon receiving from TNL a disclosure of a technical development that may improve the treatment of TB, malaria, or HCV, in accordance with Clause 7.1, MPP shall inform TNL within 120 days whether the said technical development is of interest.
- 7.3. In the event MPP wishes the technical development to be licensed to MPP and the technical development is free from any Encumbrance and is an advancement of an LAI, then TNL and MPP shall amend Schedule 1 to incorporate any relevant patents and patent applications and/or effect a suitable transfer of know-how in accordance with Clause 4.1.
- 7.4. In the event a technical development in accordance with clause 7.1 comes to have its exclusive rights vested in TNL, is free from any Encumbrance, is not an advancement of an LAI and is of interest to MPP in accordance with Clause 7.2, then TNL and MPP shall discuss in good faith a new license agreement for said technical development.

## **8. INTELLECTUAL PROPERTY MANAGEMENT**

- 8.1. Having regard to the interests of ensuring the commercialisation and continued supply of the Final Products for the benefit of the Public Sector in LMICs, TNL will (where it considers it commercially sensible to do so) maintain in force the Licensed Patents for the duration of the Agreement as set forth in Section 12.1 (unless such maintenance would be inconsistent with the Access Objective).
- 8.2. The MPP shall have no rights in relation to the conduct of any matter relating to the Licensed Patents, including the filing, prosecution and maintenance thereof.

## **9. INTELLECTUAL PROPERTY INFRINGEMENT**

- 9.1. TNL, or any third party TNL elects, will be responsible (at its own expense and discretion) for, and be in control of, the prosecution, maintenance and enforcement of all Licensed Patents.
- 9.2. TNL will have the transferable right but not any obligation to bring an infringement action and any such action shall be at its own expense and entirely under its own direction and control.
- 9.3. MPP will (at its own expense) reasonably assist TNL in any action or proceeding being prosecuted if so requested by TNL and such reasonable assistance is necessary for TNL to fully exercise its rights under such proceeding.
- 9.4. The Parties will make best efforts to ensure that the development and commercialisation of Licensed Products will not infringe any third party intellectual property rights in any jurisdiction worldwide.
- 9.5. MPP will promptly inform TNL if it becomes aware of any infringement or potential infringement of any of the Licensed Patents in the Field.

## **10. CONFIDENTIALITY**

- 10.1. Each Party agrees that, for so long as this Agreement is in effect, and thereafter, a Party receiving Confidential Information of the other Party will:
  - (i) Maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own confidential information;

- (ii) Not disclose such Confidential Information to any third party without the prior written consent of the other Party, except for disclosure expressly permitted under this Agreement; and
  - (iii) Not use such Confidential Information for any purpose except those permitted by this Agreement.
- 10.2. The obligations under clause 10.1 will not apply with respect to any portion of the Confidential Information that the receiving Party can show by written evidence:
- (i) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party; or
  - (ii) Was known to the receiving Party without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or
  - (iii) Is subsequently disclosed to the receiving Party by a third party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
  - (iv) Is published by a third party or otherwise becomes publicly available, on a lawful basis, either before or after it is disclosed to the receiving Party; or
  - (v) Has been independently developed by employees or contractors of the receiving Party without the aid, application or use of Confidential Information of the disclosing Party.
- 10.3. The receiving Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:
- (i) Regulatory filings;
  - (ii) Prosecuting or defending litigation;
  - (iii) Complying with applicable governmental laws and regulations;
  - (iv) Disclosure in connection with the performance of this Agreement and solely on a "need-to-know basis", to Affiliates, Unitaid, actual or potential donors, potential collaborators, research collaborators, employees, consultants or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this clause 10; provided however that the receiving Party will remain responsible for any failure by any such person who receives Confidential Information pursuant to this clause 10 to treat such Confidential Information as required under this clause 10.
- 10.4. The Parties agree that a copy of this Agreement as well as of each Sub-licence Agreement may be publicly disclosed on MPP's website. Such disclosure will not constitute a breach of either Party's obligations under this clause 10.
- 11. WARRANTIES AND LIABILITY**
- 11.1. TNL warrants that as of the Effective Date TNL has full ability to enter into this Agreement and the right to license the Licensed Technology and that, to the best of TNL's knowledge, there are no Encumbrances over the Licensed Technology that are inconsistent with this Agreement, and so

far as TNL is aware (it being acknowledged that TNL has not undertaken comprehensive freedom to operate searches or investigations or searches of registered intellectual property right) the development and commercialisation of the Final Products in accordance with the Project Plan will not infringe any third party intellectual property rights. Neither TNL nor MPP has granted or will grant to any third party any of its right, licence or interest in, to or under the Licensed Technology that would conflict with, limit or adversely affect the Parties' ability to comply with the terms of this Agreement.

11.2. To the fullest extent permissible by law and notwithstanding Clause 11.1, TNL does not make any warranties of any kind including, without limitation, warranties with respect to:

11.2.1. The quality of the Licensed Technology;

11.2.2. The suitability of the Licensed Technology for any particular use;

11.2.3. That any of the Licensed Patents is or will be valid or subsisting or (in the case of an application) will proceed to grant.

11.3. Neither MPP nor MPP Licensees shall directly or indirectly make a claim against any individual employee, agent or appointee of TNL, being a claim which seeks to enforce against any of them any liability whatsoever in connection with this Agreement or its subject-matter.

11.4. MPP will include appropriate obligations on MPP Licensees that indemnify TNL and every employee, agent and appointee of TNL ("the Indemnified Parties"), and keep them fully and effectively indemnified, against each and every claim made against any of the Indemnified Parties as a result of the use of or licensing of the Licensed Technology, the manufacture, use, sale of, or other dealing in any of the Licensed Products by MPP Licensees provided that the indemnity in this clause will not apply to the extent that the claim arises as a result of the Indemnified Party's negligence.

11.5. Subject to clause 11.8, and except under the indemnity in clause 11.4, the liability of either party to the other for any breach of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement will not extend to any indirect damages or losses, even if the party bringing the claim has advised the other of the possibility of those losses or if they were within the other party's contemplation.

11.6. MPP will require that the obligations set out in Clause 11 will be binding upon MPP Licensees and that MPP Licensees will indemnify TNL for any direct loss arising from a breach by a MPP Licensee of the obligation under each Sub-licence Agreement.

11.7. Subject to clause 11.8, the aggregate liability of TNL for all and any breaches of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, will not exceed £25,000.

11.8. Nothing in this Agreement limits or excludes either party's liability for death or personal injury; any fraud or for any liability that, by law, cannot be limited or excluded.

## **12. DURATION AND TERMINATION**

12.1. This Agreement will take effect on the Effective Date and, unless terminated earlier as provided herein, shall continue in force until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated.

12.2. A Party ("non-breaching party") shall have the right to terminate this Agreement in the event the other Party ("breaching party") is in material breach of any of its material obligations under

this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of 30 days after such written notice to cure such breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured within such period, or other agreed timeline, this Agreement will be deemed terminated with effect from the end of the period or timeline.

**12.3. Additional termination rights:**

12.3.1. TNL will have the right to terminate this Agreement upon written notice to MPP if development of all Licensed Technology has stopped in agreement with UNITAID.

12.3.2. Either Party will have the right to terminate this Agreement if the other party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other Party's assets, or if the other Party makes any arrangement with its creditors or takes or suffers any similar or analogous action in any other jurisdiction.

12.4. MPP may terminate this Agreement at any time by giving TNL not less than 90 days' written notice.

**13. CONSEQUENCES OF TERMINATION**

13.1. In the event that this Agreement is terminated other than under Section 14.1, all Sub-Licence Agreements will, upon written approval by TNL, such consent not to be unreasonably withheld, be converted into licences between TNL and the MPP Licensees, provided that the MPP Licensee is not in breach of the Sub-Licence Agreement, by way of the MPP, TNL and the relevant Licensee entering into a novation agreement transferring the rights and obligations of the MPP under the Sub-licence to TNL.

13.2. On termination or expiration of this Agreement, in the event that any MPP Licensees are not converted into licences between TNL and the MPP Licensee under Clause 13.1, MPP shall procure that MPP Licensees are terminated and immediately provide TNL with details of the stocks of Licensed Products held at the point of termination.

13.3. Clauses 10, 11.2, 11.3, 11.5, 11.7, 11.8, 13, and 14 will survive the expiry or termination of this Agreement.

**14. GENERAL**

14.1. Force Majeure: If the performance by either party of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by circumstances beyond its reasonable control, that party will not be in breach of this Agreement because of that delay in performance. However, if the delay in performance is more than 3 months, the other party may terminate this Agreement with immediate effect by giving written notice.

14.2. Notices: Any notice to be given under this Agreement must be in writing, may be delivered to the other party's representative as detailed below, and as updated from time to time:

**For TNL:**  
Name: Antony Odell

**For MPP:**  
Name: General Counsel

Address: C/O The University of Liverpool IP Commercialisation, 1st Floor Blk D, Waterhouse Building 3 Brownlow St, Liverpool, L22 3GL, United Kingdom  
Email: antony.odell@tandemnano.com

Address: Rue de Varembe 7 1202 Geneva Switzerland  
Email: cpark@medicinespatentpool.org

and by any of the methods set out below, and will be deemed to be received as set out below:

By hand or courier: the day of delivery and is sent concurrently by email  
By pre-paid first class post: the second working day after posting and is sent concurrently by email

- 14.3. Assignment/Change in Control: neither Party may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other Party. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

Furthermore, in the event of either:

- (a) a Change in Control; or
- (b) the license, transfer, sale, spin-off or acquisition of the Licensed Technology, or of substantial assets owned or controlled by TNL which are necessary to perform its obligations hereunder, or by a third party, including as a result of a Change of Control;

TNL will ensure that such licensee, purchaser, transferee, acquirer or successor of the Licensed Technology or TNL's assets agrees to be bound by the terms of this Agreement, in a written form agreement acceptable to MPP.

- 14.4. Waiver of rights: If a Party fails to enforce, or delays in enforcing, an obligation of the other Party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.
- 14.5. No agency: Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the Parties, or the relationship between them of principal and agent. Neither party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.
- 14.6. Entire agreement: This Agreement constitutes the entire agreement between the Parties relating to its subject matter. Each Party acknowledges that it has not entered into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. For the avoidance of doubt, nothing in this Agreement shall prevent either Party from developing any research programs and entering into further collaborations with third parties, provided that they are not in breach of this Agreement and its Schedules.
- 14.7. Conflicts: In the event that there is a conflict between the terms of the main body of this Agreement and its Schedules, the former shall prevail.
- 14.8. Further assurance: Each Party will take any action and execute any document reasonably required by the other Party to give effect to any of its rights under this Agreement, or to enable

- their registration in any relevant territory provided the requesting Party pays the other Party's reasonable expenses.
- 14.9. Amendments: No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative.
- 14.10. Third parties: No one except a Party to this Agreement has any right to prevent the amendment of this Agreement or its termination, and, save in relation to clauses 11.3 and 11.4 no one except a party to this Agreement may enforce any benefit conferred by this Agreement.
- 14.11. Severability: If any of the provisions of this Agreement is or becomes invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions will not in any way be affected or impaired. Where necessary the Parties will negotiate in good faith mutually satisfactory amendments achieving as nearly as possible the same effect to replace the provisions found to be void or unenforceable.
- 14.12. Resolution by senior executives: All disputes, controversies or claims between the Parties in connection with this Agreement, its construction, or the rights, duties or liabilities of either Party under this Agreement (a "Dispute") must be resolved pursuant to the following resolution process in this clause 14.12 and the jurisdiction clause 14.13. The Parties to any dispute may alter or amend these procedures by agreement in writing.
- 14.12.1. To commence the resolution process, any Party may serve notice to the other Party identifying: (i) the nature of the Dispute; and (ii) the amount in Dispute.
- 14.12.2. Once notice is received, the parties must first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves.
- 14.12.3. In the event that such Dispute is not resolved on an informal basis within 30 days after such notice is received, either Party may, by written notice to the other Party, refer the Dispute to the Executive Director in the case of the MPP and to Executive Chairman in the case of TNL (together the "Designated Officers") for attempted resolution by good faith negotiation.
- 14.12.4. If any Dispute is not resolved by the Designated Officers, then either Party may seek resolution by the English Courts, in accordance to clause 14.13
- 14.13. Governing law: This Agreement is governed by, and is to be construed in accordance with, English law. Except as provided in clause 14.12 if any dispute is not resolved by the Designated Officers, then the English Courts will have exclusive jurisdiction to deal with any Dispute which has arisen or may arise out of, or in connection with, this Agreement.

*[signatures appear on following page]*

**SIGNED on behalf of TNL:**

Antony Odell

.....  
**Name**

Executive Chair

.....  
**Position**

.....  
**Signature**



8/31/2021

.....  
**Date**

**SIGNED on behalf of MPP:**

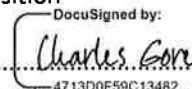
Charles Gore

.....  
**Name**

Executive Director

.....  
**Position**

.....  
**Signature**

DocuSigned by:  


4713D0F59C13482  
8/30/2021

.....  
**Date**



**Schedule 1**  
**The Licensed Patent(s):**

Patent Type	Patent title	Patent Status	Country	Patent Application Number	Priority Date	Grant Number
PCT	Method of Preparing Carrier Liquids		WO	PCT/GB2012/052028	31/08/2011	
National		Granted	US	14/241,965	31/08/2011	9718036
Regional		Granted	EP	12753233.1	31/08/2011	
National		Granted	IN	697/KOLNP/2014	31/08/2011	313481

PCT	Improvements relating to Antiviral compositions		WO	PCT/GB2011/000549	08/04/2011	
National		Granted	US	13/640653	08/04/2011	9192584
Divisional		Granted	US	14/862875	08/04/2011	9820939
Divisional		Pending	US	15/728870	08/04/2011	
Regional		Pending	EP	11715996.2	08/04/2011	
National		Pending	IN	3298/KOLNP/2012	08/04/2011	
National		Granted	IL	222266	08/04/2011	222266
Divisional		Pending	IL	254176	08/04/2011	
National		Pending	CN	201180028879.5	08/04/2011	
Divisional		Pending	CN	201711286726.6	08/04/2011	

PCT	Improvements relating to Anti-parasitic compositions		WO	PCT/EP2007/056561	13/07/2006	
Regional		Granted	EP	07765733.6	13/07/2006	2040677
National		Granted	GB	07765733.6	13/07/2006	2040677
National		Granted	DE	07765733.6	13/07/2006	2040677
National		Granted	SE	07765733.6	13/07/2006	2040677
National		Granted	FR	07765733.6	13/07/2006	2040677
National		Granted	IT	07765733.6	13/07/2006	2040677
National		Granted	ES	07765733.6	13/07/2006	2040677
National		Granted	NL	07765733.6	13/07/2006	2040677
National		Granted	BE	07765733.6	13/07/2006	2040677
National		Granted	CH	07765733.6	13/07/2006	2040677
National		Granted	IE	07765733.6	13/07/2006	2040677
National		Granted	AT	07765733.6	13/07/2006	2040677

PCT	Chemical Composition (Atovaquone formulations)		WO	PCT/GB2017/051746	16/06/2016	
National		Pending	US	62/310199	16/06/2016	
Regional		Pending	EP	17736703.4	16/06/2016	
National		Pending	IN	201937001054	16/06/2016	
National		Pending	CN	201780050248.0	16/06/2016	
National		Pending	AU	2017286626	16/06/2016	
National		Pending	ARIPO	AP/P/2018/011250	16/06/2016	
National		Pending	ZA	2019/00142	16/06/2016	
National		Pending	JP	2018-565810	16/06/2016	

**END OF SCHEDULE 1**

**Schedule 2**  
**The Territory**

All LMICs as at the Effective Date as detailed below. In the event that the World Bank changes its own classification of LMICs following the Effective Date, the parties may, by agreement in writing, amend the Territory accordingly.

Afghanistan	Dominica	Lebanon	Senegal
Albania	Dominican Republic	Lesotho	Serbia
Algeria	Ecuador	Liberia	Sierra Leone
American Samoa	Egypt, Arab Rep.	Libya	Solomon Islands
Angola	El Salvador	Madagascar	Somalia
Argentina	Equatorial Guinea	Malawi	South Africa
Armenia	Eritrea	Malaysia	South Sudan
Azerbaijan	Eswatini	Maldives	Sri Lanka
Bangladesh	Ethiopia	Mali	St. Lucia
Belarus	Fiji	Marshall Islands	St. Vincent And The Grenadines
Belize	Gabon	Mauritania	Sudan
Benin	Gambia, The	Mexico	Suriname
Bhutan	Georgia	Micronesia, Fed. Sts.	Syrian Arab Republic
Bolivia	Ghana	Moldova	Tajikistan
Bosnia And Herzegovina	Grenada	Mongolia	Tanzania
Botswana	Guatemala	Montenegro	Thailand
Brazil	Guinea	Morocco	Timor-Leste
Bulgaria	Guinea-Bissau	Mozambique	Togo
Burkina Faso	Guyana	Myanmar	Tonga
Burundi	Haiti	Namibia	Tunisia
Cabo Verde	Honduras	Nepal	Turkey
Cambodia	India	Nicaragua	Turkmenistan
Cameroon	Indonesia	Niger	Tuvalu
Central African Republic	Iran, Islamic Rep.	Nigeria	Uganda
Chad	Iraq	North Macedonia	Ukraine
China	Jamaica	Pakistan	Uzbekistan
Colombia	Jordan	Papua New Guinea	Vanuatu
Comoros	Kazakhstan	Paraguay	Venezuela, Rb

Congo, Dem. Rep.	Kenya	Peru	Vietnam
Congo, Rep.	Kiribati	Philippines	West Bank And Gaza
Costa Rica	Korea, Dem. People's Rep.	Russian Federation	Yemen, Rep.
Cote D'ivoire	Kosovo	Rwanda	Zambia
Cuba	Kyrgyz Republic	Samoa	Zimbabwe
Djibouti	Lao Pdr	Sao Tome And Principe	

**Schedule 3**  
**Development Agreement Term Sheet**

1. **Scope of the grant:** MPP will grant a non-exclusive, non-transferable worldwide licence under the Licensed Technology to allow Development Partners to develop, or have developed, Licensed Technology into Licensed Products in the Field. For the avoidance of doubt, Development Partner will be expressly prohibited from further sub-licensing the Licensed Technology to any other third party.
2. **Term:** The Sub-licence Agreement will be in force from the date of its signature until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated. MPP shall have the right to either terminate the Development Agreement, or to require the Development Partner to novate the Development Agreement to TNL (i.e. by entering into a Novation Agreement with MPP and TNL), in the event that the MPP-TNL Agreement is terminated.
3. **Improvements:** If at any time during the term of the Sub-licence Agreement the Development Partner (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it will communicate such Improvement to MPP and TNL in full together with all available information concerning the mode of working and using the same. MPP and TNL will treat this information as confidential. To the extent that the Development Partner is under a contractual obligation to provide access to any Improvement to a third party, in no event is the Development Partner authorised to provide access to any Licensed Technology without TNL's written consent.
4. **Grant-back rights:** Development Partner will grant to MPP and TNL a perpetual, irrevocable, worldwide, royalty-free, non-exclusive, sub-licensable licence over any Improvement (and shall promptly execute such document as TNL may reasonably request accordingly). Such licence will not affect the Licensee's ownership of the Improvements. MPP will have the right to sub-licence such rights to its Commercialisation Partner(s).
5. **Waiver of data exclusivity rights:** Development Partner agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Licensed Products.
6. **Warranty & Indemnity:** The Development Partner will acknowledge and agree that the Licensed Technology is licensed to Licensee "as is". TNL and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Development Partner. The Development Agreement will include indemnification and limitation of liability provisions consistent with Clause 11 of the MPP-TNL Agreement.
7. **Timelines:** The Development Agreement will include time lines for the development of Licensed Technology into Licensed Products.
8. **Reporting:** Within ten (10) business days following the end of each calendar quarter, Development Partner will be required to provide MPP and TNL with a quarterly written report setting forth in relation to that quarter the following: (a) summary of project implementation and current schedule of anticipated events or milestones including status of readiness of labs,

- plants, machinery as required, (b) details of project related specific recruitments and a summary of resources (dollar value) spent in the reporting period if any, (c) Licensed Products in its development pipeline, (e) status of development of each Licensed Product in development, (f) any scientific discoveries or Know-how developed; (g) any other information that MPP and TNL may require to monitor progress and implementation of the projects. MPP and Licensee will agree to meet on a quarterly basis regarding such reports. MPP agrees that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with TNL, MPP's funders, TNL's funder, and funders, if any, of the project under consideration; and that status update may be publicly disclosed by the MPP or TNL. Within thirty (30) days of the end of the Development Partner's programme they will deliver to MPP and TNL a complete dossier of information allow MPP to effect an efficient technology transfer to the Commercialisation Partner and TNL to effect an efficient technology transfer to its licensees including its licensees outside the Territory.
9. **Audit:** The Development Partner will permit MPP and TNL, individually or together, and when required, through a certified public accountant to: (i) inspect and audit the performance of, and compliance with, the Development Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Development Agreement. Development Partner will cooperate with and provide all reasonable assistance to MPP or TNL. MPP or TNL will provide Development Partner with a commercially reasonable period of notice of the proposed audit. MPP and TNL, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Development Partner to perform in compliance with the Development Agreement or applicable laws. If any audit reveals a discrepancy of more than 5% to the detriment of TNL and/or MPP, Development Partner will reimburse MPP or TNL for the cost of that audit.
  10. **Confidentiality:** Confidentiality obligations similar to those established in Clause 10 of the Agreement will be included in the Development Agreement. Confidential Information exchanged under the Development Agreement may be shared with TNL and UNITAID.
  11. **Trademarks and names:** Development Partner will not use TNL's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of promotional material other than for the purposes of complying with the Development Agreement, without the prior written agreement of both MPP and TNL.
  12. **Third Party Rights:** TNL will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Development Agreement with the Development Partner.
  13. **Governing Law/ADR:** The governing law for the Development Agreement will be the laws of England in a court of law in England. All disputes will be resolved via an alternative dispute mechanism to be set forth in the agreement.
  14. **Eligibility:** The Development Partner will be eligible to become a Commercialisation Partner by executing a separate Commercialisation Agreement in accordance with Schedule 4.
  15. **Compliance with Laws:** The Development Partner shall ensure, solely at its own expense, that its performance, the Licensed Technology and the Licensed Products comply with all applicable laws, rules, regulations, orders, decrees, judgments and other governmental acts of any foreign governmental authorities having jurisdiction over the Development Partner (including

any health and safety rules and regulations and any patent, copyright, trademark or other infringement laws), and that it will hold prior to any applicable activities related to the Licensed Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to develop or have developed the Licensed Product.

16. Additional Terms: The Development Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-TNL Agreement, as well as other mutually agreeable language regarding other additional customary terms.

**Schedule 4**  
**Commercialisation Agreement Term Sheet**

1. **Scope of the grant:** MPP will grant a Commercialisation Partner a non-exclusive, non-transferable royalty-free worldwide licence under the Licensed Technology to allow Commercialisation Partners to make, have made, use, offer for sale, sell, have sold, export and import the Licensed Products for the purposes of commercialising Licensed Products in the Field and exclusively for administration to patients in the Territory.

For the avoidance of doubt Commercialisation Partner will be expressly prohibited from further sub-licensing the Licensed Technology to any other third parties.

2. **Access Commitments:** Commercialisation Partners will ensure that Licensed Products are made available in accordance with the following specific access commitments (the "Specific Access Commitments"):
  - a. **Price Commitment:** the Licensed Products will be made available in the Territory at a price which is no more than the Affordable Price;
  - b. **Supply Commitment:** the Licensed Products will be made available in a timely manner and in sufficient quantities to meet the needs of the Public Sector in the Territory, including in accordance with any Minimum Supply Targets, and shall prioritise delivery of firm orders from the Public Sector over firm orders from the Private Sector. Commercialisation Partner shall make best efforts to ensure that the Final Product can be purchased by the Public Sector in the Territory through relevant governmental or international procurement mechanisms including, without limitation, Global Fund, PEPFAR and the Global Drug Facility ("GDF"). The said efforts shall include, without limitation, responding to tenders launched by such procurement mechanisms.
  - c. **Registration Commitment:** the Licensed Products will be registered in certain priority countries as designated by MPP, upon agreement with Unitaidd to determine the registration plan and timeline.
  - d. **QA Commitment:** the Licensed Products will be developed in accordance with appropriate quality standards and Commercialisation Partners will seek approval or a positive recommendation for Licensed Products from the WHO Prequalification Programme (PQ), Global Fund/Unitaid Expert Review Panel (ERP), US FDA and/or another WHO Listed Regulatory Authority as agreed between MPP and the Commercialisation Partner.
3. **Manufacturing Commitment:** Commercialisation Partner will make commercially reasonable efforts to manufacture Licensed Products at the lowest possible cost and will pass on any significant reduction in the production and distribution costs of the Licensed Products to the benefit of the sale price offered to the Public Sector.
4. **Term:** The Commercialisation Agreement will be in force from the date of its signature until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated. MPP shall have the right to either terminate the Commercialisation Agreement, or to require the Commercialisation Partner to novate the Commercialisation Agreement to TNL (i.e. by entering into a Novation Agreement with MPP and TNL), in the event that the MPP-TNL Agreement is terminated. Upon termination,

Commercialisation Partner will immediately provide MPP with details of the stocks of Licensed Products held at the point of termination.

5. **Improvements:** If at any time during the term of the Commercialisation Agreement the Commercialisation Partner (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to MPP and TNL in full together with all available information concerning the mode of working and using the same. MPP and TNL shall treat this information as confidential. To the extent that the Commercialisation Partner is under a contractual obligation to provide access to any Improvement to a third party, in no event is the Development Partner authorised to provide access to any Licensed Technology without TNL's written consent.
6. **Grant-back rights:** Commercialisation Partner will grant to MPP and TNL a perpetual, irrevocable, worldwide, royalty-free, non-exclusive, sub-licensable licence over any Improvement (and shall promptly execute such document as TNL may reasonably request accordingly). Such licence will not affect the Commercialisation Partner's ownership of the Improvements. Commercialisation Partner will agree to engage in good-faith negotiations should MPP desire to further sublicense such Improvements. TNL shall be entitled to grant sub-licences (without further right to sublicense) to other third parties, provided that it will be prohibited from sublicensing to a Direct Competitor (to be defined in the Commercialisation Agreement) of the Commercialisation Partner in the Territory without its written consent.
7. **Waiver of data exclusivity rights:** Commercialisation Partner agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Licensed Products.
8. **Warranty & Indemnity:** The Commercialisation Partner will acknowledge and agree that the Licensed Technology is licensed to Commercialisation Partner "as is". TNL and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Licensee. The Commercialisation Agreement will include indemnification and limitation of liability provisions consistent with Clause 11 of the MPP-TNL Agreement.
9. **Timelines:** The Commercialisation Agreement will include timelines for the development, regulatory approvals and placing of the Licensed Products in the market.
10. **Reporting:** Within 10 business days following the end of each calendar quarter, Commercialisation Partner will be required to provide MPP and TNL with a quarterly written report setting forth in relation to that quarter (a) Licensed Products in its development pipeline, (b) status of development of each Licensed Product in development, (c) regulatory filing plan for each Licensed Product, (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been filed or obtained for any Licensed Product and (e) the Licensed Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under the Commercialisation Agreement during such agreement quarter, on a country-by-country basis; (f) any scientific discoveries or Know-how developed related to the Licensed Technology. MPP and Licensee will agree to meet on a quarterly basis regarding such reports and also review development and filing status of Licensed Products. MPP will agree that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with TNL and Unitaïd; and that aggregated data may be publicly disclosed by MPP.



11. **Audit**: Commercialisation Partner will permit MPP and TNL, individually or together, through a certified public accountant to: (i) inspect and audit the performance of, and compliance with, the Commercialisation Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Commercialisation Agreement. Commercialisation Partner will cooperate with and provide all reasonable assistance to MPP or TNL. MPP or TNL will provide Commercialisation Partner with a commercially reasonable period of notice of the proposed audit. MPP and TNL, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Licensee to perform in compliance with the Commercialisation Agreement or applicable laws. If any audit reveals a discrepancy of more than 5% to the detriment of TNL and/or MPP, Commercialisation Partner will reimburse MPP or TNL for the cost of that audit. The result of the audit will be binding, and in the event that the audit reveals a failure to comply with the Price Commitment, the Commercialisation Partner will implement any adjustment to the Affordable Price deemed required by MPP or TNL as a result of the audit.
12. **Confidentiality**: Confidentiality obligations similar to those established in Clause 12 of the Agreement will be included in the Commercialisation Agreement. The Confidential Information exchanged under the Commercialisation Agreement may be shared with TNL and Unitaid.
13. **Trademarks and names**: Commercialisation Partner will not use TNL's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of packaging and promotional material other than for the purposes of complying with the Commercialisation Agreement, without the prior written permission of both MPP's and TNL's authorised representative. Licensed Product manufactured under the Commercialisation Agreement will be marked (to the extent not prohibited by law): (i) with a notice that such Licensed Product is sold under a license from TNL and MPP; and (ii) with all markings and notices as may be required by applicable law, including in relation to patent and other intellectual property.
14. **Third Party Rights**: TNL, will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Commercialisation Agreement with the Commercialisation Partner.
15. **Governing Law/ADR**: The governing law for the Commercialisation Agreement will be the laws of England in a court of law in England. All disputes will be resolved via an alternative dispute mechanism to be set forth in the Commercialisation Agreement.
16. **Compliance with Laws**: Commercialisation Partner shall ensure, solely at its own expense, that its performance, the Licensed Technology and the Licensed Products comply with all applicable laws, rules, regulations, orders, decrees, judgments and other governmental acts of any foreign governmental authorities having jurisdiction over the Commercialisation Partner (including any health and safety rules and regulations and any patent, copyright, trademark or other infringement laws), and that it will hold prior to any applicable activities related to the Licensed Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to use, design, develop, produce, manufacture, offer for sale, sell, distribute, import and export the Licensed Product.
17. **Insurance**: Within 30 days prior to the first commercial launch by Commercialisation Partner of a Licensed Product, and each year thereafter for so long as the Commercialisation Agreement is in effect, Commercialisation Partner shall provide to MPP certificates of

insurance by insurers acceptable to MPP evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than 10 million dollars (\$10,000,000.00) for bodily injury, including personal injury, and property damage.

18. Additional Terms: The Commercialisation Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-TNL Agreement, as well as other mutually agreeable language regarding other additional customary terms.